# REQUEST FOR COMPETITIVE SEALED PROPOSALS RFP NO. FY08-100

Pursuant to the Arizona Administrative Code (A.A.C.) R2-7-104, the Offerors may designate portions of proposals submitted under this RFP as proprietary. Documents incorporated by reference in this RFP package may be reviewed during normal business hours at:

# Arizona Biomedical Research Commission 15 South 15<sup>th</sup> Avenue, Suite 103-A Phoenix, Arizona 85007

**ARIZONA PROCUREMENT CODE:** The Arizona Procurement Code (Ariz. Rev. Stat.§41-2501 to 41-2673) and the Arizona Procurement Code Rules and Regulations (A.A.C. R2-7-101 to R2-7-1010) are a part of this document as if fully set forth herein.

STATE PURCHASING OFFICE (SPO) VENDOR NUMBER: You may obtain a SPO Vendor Number by completing the Vendor Registration Application. Please contact SPO for a Vendor Registration packet:

State Procurement Office Arizona Department of Administration 100 North 15<sup>th</sup> Avenue, Suite 104 Phoenix, Arizona 85007 (602) 542-5511

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## **TIMETABLE**

Advertisements of Legal Notice will run the weeks of	October 22 and November 5, 2002
Deadline for Receipt of Requests for Technical Assistance	November 8, 2007
Deadline for Submission of Proposals	December 3, 2007
Proposal Opening	December 4, 2007
Proposed Term of Contract(s) Awarded under this RFP	July 1, 2008 to June 30, 2009, 2010 or 2011

# **PROPOSAL INSTRUCTIONS**

The Arizona Biomedical Research Commission is requesting proposals from individuals, organizations, corporations and institutions, public or private, in this state for: projects or services that may advance research into the "the prevention and treatment of tobacco related disease and addiction and research into the causes, epidemiology and diagnosis of diseases, the formulation of cures, the medically accepted treatment or the prevention of diseases including new drug discovery and development and may include behavioral studies and attitude assessments." Please note graduate students and post-doctoral fellows are not eligible to be named as principal investigators for an ABRC contract.

#### **PRIORITY AREAS**

- A. Accidents and Trauma including the Health Effects of Environmental Pollutants
- B. Bioengineering and Bioimaging
- C. Cancer
- D. Cardiovascular, Cerebrovascular, Peripheral Vascular, and Pulmonary Disease
- E. Genetics, Genomics, and Proteomics
- F. Health Policy, Health Promotion and Disease Prevention
- G. Infectious and Immunological Diseases and Disorders
- H. Metabolic and Endocrine Disorders
- I. Neuroscience, Neurological, Mental and Behavioral Diseases and Disorders
- J. Miscellaneous Diseases or Disorders not previously categorized

In accordance with the attached Work Statement and application package, services are sought **Statewide**.

Proposals are limited to total budget requests of *no more than* \$50,000 per year. This amount **includes** a maximum indirect cost rate of 10 percent. These proposals may request funding for no more than three years. It is expected that these projects will be designed as pilot research that will elicit further extramural support and encourage new investigators, and/or as research with a limited scope.

## A COST OR PRICING DATA

Cost or pricing data is required under this RFP.

# B. TECHNICAL ASSISTANCE

Written, faxed, or emailed questions for technical assistance shall be in writing and shall be submitted to Executive Director
Arizona Biomedical Research Commission
15 South 15<sup>th</sup> Avenue, Suite 103-A

Phoenix, Arizona 85007

# 2. The deadline for receipt of written questions is 4:00 p.m., November 8, 2007.

Commission responses to questions for technical assistance shall be mailed to each RFP recipient within seven (7) working days after the submission deadline.

# 3. Verbal Requests for Technical Assistance

Verbal requests for technical assistance will not be accepted.

## D. AMENDMENTS TO RFP

Any and all amendments to this RFP shall be sent to all RFP recipients by first class mail. Copies of amendments must be signed by the Principal Investigator and returned with the proposal.

# E. SUBMISSION OF PROPOSALS

One original proposal and seven (7) copies must be **received** (not postmarked), in a **sealed** envelope or box **clearly marked "PROPOSAL RFP No. FY08-100" no later than 4:00 p.m. on December 3, 2007** the Arizona Biomedical Research Commission, 15 South 15<sup>th</sup> Avenue, Suite 103-A, Phoenix, Arizona 85007. No facsimiles or e-mails will be accepted. **Late proposals will not be accepted or considered.** 

#### F. PROPOSAL OPENING

Proposals shall be opened publicly at the place and time specified below:

Place:

Arizona Biomedical Research Commission 15 South 15<sup>th</sup> Avenue, Suite 103-A Phoenix, Arizona 85007

Time and Date:

9:00 a.m., December 4, 2007

# G. POST-PROPOSAL SUBMISSION DISCUSSIONS AND REVISIONS

- 1. Discussions may be conducted with responsive offerors who submit proposals determined to have a reasonable chance of being selected.
- 2. In conducting discussions, there shall be no disclosure of information derived from competing offerors.
- 3. Proposal revisions **shall** be permitted after the submission and before award for the purpose of obtaining best and final offers.

#### H. MULTI-YEAR CONTRACTS

Contracts with the Arizona Biomedical Research Commission may be entered into for a period not to exceed three years, as deemed in the best interest of the State. Awards of more than one year are contingent upon the availability of funds, demonstration of sufficient progress toward Contract goals and timely submission of required reports. Contracts may be terminated for failure to make timely required reports.

2. If monies are not appropriated or otherwise made available to support continuation of performance in a subsequent fiscal period, the Contract shall be cancelled and the Contractor may only be reimbursed for the reasonable value of any nonrecurring costs incurred but not amortized in the price of the materials or services delivered under the Contract or which are otherwise not recoverable. The cost of cancellation may be paid from any funds available for such purposes.

Projects under this RFP are limited to total budget requests of **no more than** \$50,000 **per year**. This amount **includes** a maximum indirect cost rate of 10 percent. These proposals may request funding for no more than three years. It is expected that these projects will be designed as: 1) encouraging new investigators, 2) pilot research projects designed to obtain the preliminary data necessary to apply for extramural funding, and 3) research with a limited scope.

# I. EVALUATION FACTORS and CRITERIA

The following factors and criteria shall be used to evaluate proposals submitted in response to this RFP. Where the same term is used to describe the relative importance of more than one evaluation factor, those evaluation factors are deemed of equal importance.

Ev	aluation Factors:	Relative Importance
	Scientific merit, including: study design, methodology, feasibility, evaluative content and importance of the proposed research.	Maximum
2.	Relevance of the proposed research to Arizona residents. Proposals representing continuing ABRC research involving technology development issues may be given favorable consideration.	Maximum
3.	Novelty and originality of the proposed research or research methodology.	Maximum
4.	Adequacy of facilities and staff, including: personnel and equipment capable of supporting the proposed research, expertise and competence of staff in the techniques required for performance and in the field of proposed investigation.	Maximum
5.	Appropriateness of the budget request: the proposed budget will be evaluated to assure that it is reasonable relative to the proposed research and that the expenditures are justifiable.	Moderate

#### J. REVIEW PROCESS - ALL PROPOSALS

First level of review: STAFF REVIEW

All proposals are reviewed for compliance and responsiveness with Request for Proposals. Proposals shall be eliminated from further review if determined to be materially incomplete according to the instructions set forth in the RFP. Submissions must follow the required format and be in the correct order.

## 2. Second level of review: PEER REVIEW (EXTERNAL)

Technical evaluations are obtained from out-of-state peer reviewers. Qualified out of state peer reviewers are scientific, health and medical experts recruited in accordance with the fourteen priority research areas that have been established by the Commission. The Commission makes every effort to obtain three outside peer reviews for each proposal. All proposals must include the name, address, phone number, and/or e-mail address of at least three (3) out-of-state reviewers that would be qualified to review the proposal.

## 3 Third level of review: COMMISSION REVIEW

The Commissioners form sub-committees to review the proposals submitted in response to the RFP. Each sub-committee reviews a portion of the proposals in their entirety, all of the lay summaries, and all of the peer reviews. The ABRC has three lay members. Investigators must describe the proposed research in clear, concise, non-scientific language in the lay summary. The lay summary and scientific narrative must state the research OBJECTIVE clearly. What the investigator plans to accomplish must be made clear and understandable to the lay reader. Information in the lay summary will be published and provided to members of the public requesting information. If a proposal has not been reviewed or has only been partially reviewed by the panel of external peer reviewers, the Commission may, nevertheless, review and consider the proposal.

#### K. CANCELLATION

The Commission reserves the right to cancel this solicitation and any or all proposals may be accepted, modified or rejected in whole or in part. Applicants are advised not to automatically expect three years of support if selected for funding even if their proposal contains a request for three years. Awards may be made for a shorter period. Funding amounts given in paragraph H is the absolute maximum amount.

# L. NOTIFICATION OF CONTRACT AWARD

Each offeror shall be notified in writing of the Commission's decision to select or reject the proposal for a contract award.

2. Unless otherwise notified, applicants that receive an award may consider their proposal approved for the duration of their award. All Contract awards are made subject to the availability of funds. Additionally, continuation of Contracts is subject to demonstration of sufficient progress toward Contract goals and timely submission of required reports. Principal investigator reports that are repeatedly more than 60 days overdue may result in contract termination.

#### M. COMPONENTS OF COMPLETE PROPOSAL

The completed proposal in response to this RFP shall consist of the following components in the order listed: Warning: proposals missing sections or not following formatting instructions will be returned without consideration. See Check List for correct submission order.

- 1. Abstract form included in RFP packet
- 2. Lay Summary form included in RFP packet
- 3. Completed Work Statement form included in RFP packet
- 4. Completed Budget Worksheets forms included in RFP packet
- 5. Letter of Assurance sample included in RFP packet
- 6. Letters of Support if offered
- 7. General Provisions- Review the General Provisions and retain a copy for your records. A copy of the General Provisions provided in the RFP packet must be attached to the original proposal only.
- 8. One original proposal and seven (7) copies shall be submitted. The proposals shall be clipped together with binder clips. Do not submit bound or stapled proposals. Label the proposal with original signatures, "ORIGINAL" at the top of the Abstract and place it on top. If your proposal contains original photographs or other materials that are necessary for the peer reviewers, you may mark 3 of the 7 copies as "PEER REVIEWER COPY" at the top of the Executive Summary. These 3 copies shall be placed directly beneath the ORIGINAL.
- 9. A list of three out-of-state reviewers qualified to review your proposal.

#### N. CERTIFICATE OF INSURANCE

Insurance shall conform to the General Provisions of the contract. The State of Arizona Certificate of Insurance, RM-7200.1(4/89) shall be completed by offeror's insurance company/authorized representative and shall be submitted to the Commission with the successful Offerors signed contract. The Contractor shall be responsible for providing an updated Certificate of Insurance should any policy terminate during the term of the contract. Arizona's three public universities and state agencies are not required to submit a Certificate of Insurance.

## O. SPECIAL REQUIREMENTS

- 1 All research proposals involving human or animal subjects must be submitted to the Principal Investigator's affiliated Institutional Human and/or Animal Subjects Review Committee, established in accord with Guidelines of the U.S. Department of Health and Human Services, prior to beginning the project. Contracts may not be finalized until institutional approval is granted. The project budget must also be approved by an institution's fiscal officer, if applicable.
- 2. Funds received from the Arizona Biomedical Research Commission shall not be used for capital construction projects.
- 3. As a general rule, a Principal Investigator is not eligible to receive more than one award in response to the RFP. Principal Investigators may, however, submit more than one proposal in a given year. When more than one proposal is submitted, the Commissioners will decide which, if any, of the proposals will be funded. Principal Investigators holding a Commission Contract are encouraged not to apply for a new award unless the proposal is being submitted in the final contract year, or unless the Principal Investigator only possesses a one-year Contract.

#### P. COST OF PROPOSAL PREPARATION

The state shall not reimburse the cost of developing, presenting, or providing any response to this solicitation.

The Request for Competitive Sealed Proposal forms (two pages) may be found at the end of the RFP.

#### **ABSTRACT**

# Principal Investigator:

# Title of Project:

The abstract is concise summary of the project's broad, long-term, and specific aims, as related to the research being proposed. Describe concisely the research design and methods for achieving the goals. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the proposal is funded, the abstract, as is, will become public information. Therefore, do not include proprietary/confidential information. The abstract is different from the Lay Summary. Do not exceed 150 words in the abstract.

# LAY SUMMARY

# INSTRUCTIONS FOR COMPLETING WORK STATEMENT

The following items shall be completed in the Work Statement by the Offeror in accordance with these instructions:

# A. NOTICES, CORRESPONDENCE AND REPORTS:

## Payment and Billing Method:

Payments shall be made within sixty (60) days of receipt of complete and accurate progress and expenditure reports

from the Contractor.

# 2. Program Reporting Requirements:

#### a. Expenditure Reports

The Contractor shall submit to the Commission Quarterly Expenditure Reports. The first three reports must be filed within thirty (30) days of the end of each quarter. The Annual Expenditure Report must be filed within sixty (60) days of the end of the fourth quarter.

#### b. Progress Reports

The Contractor shall submit Quarterly Progress Reports to the Commission. The first three Quarterly Progress Reports are due thirty (30) days after the end of each quarter. An Annual Progress Report must be filed within sixty (60) days of the end of the fourth quarter.

#### c. Other Reports

The Contractor shall submit such other reports as may be required by the Commission for the purpose of determining contract performance. Supplementary materials may be requested at the Commission's discretion at any time during the contract period.

d. Notices, Correspondence, Reports, and Payments from the Contractor shall be sent to:

Executive Director Arizona Biomedical Research Commission 15 South 15<sup>th</sup> Avenue, Suite 103-A Phoenix, Arizona 85007 Phone: (602) 542-1028

# 3. RESEARCH NAME AND ACTIVITY:

More than one page may be used when responding to each of the items. To continue the Work Statement for each activity, use only the work statement blank form which is attached at the end of this section Make as many copies as you need. Offerors are urged to limit their responses to the Statement of Work Criteria to twenty (20) printed, single-spaced pages using standard type sizes of 10 point or larger for word processed documents. Each section must be clearly labeled.

# 4. TABLES, CHARTS, PHOTOS AND DIAGRAMS

Place table, charts, photos, and diagrams in their appropriate location in the text. Number and caption each.

# B. STATEMENT OF WORK CRITERIA AND CHECKLIST

Utilize the enclosed sample Work Statement sheet and as many pages as necessary for each Statement of Work Criteria Begin each section on a new sheet with the title of each criterion listed at the top of each page. Work Statement pages must be consecutively numbered.

# **ACTIVITY: Goals and Objectives**

List the specific aims, goals and objectives of the proposed research, and the hypothesis (es) to be tested.

## 2. BACKGROUND INFORMATION AND LITERATURE REVIEW

Include a narrative introduction to your proposal providing relevant background information. The narrative should not exceed five (5) pages. An annotated bibliography of the relevant literature **shall** be included. It is recommended that the list be limited to five (5) pages.

#### 3 PRELIMINARY WORK

A list of all studies and publications related to the research proposal previously completed by the Offeror shall be included, if appropriate.

#### 4. ACTIVITY: Experimental Methodology

Outline the experimental design and procedures to be used to accomplish the specific aims, goals and objectives of the project. Describe any new methodology and its advantage(s) over existing methodologies. Point out any procedures, situations or materials that may be hazardous to personnel.

#### 5 ACTIVITY: Data Analysis

Describe the means by which the data will be collected, analyzed and interpreted. Discuss potential difficulties and limitations of the proposed techniques.

#### 6. ACTIVITY: Timeline

Provide a chronological outline in regard to goals, objectives, methods and data analysis. Define as clearly as possible the progression of the research plan over the year(s).

#### 7 ACTIVITY: Evaluation

Discuss how you will ensure that the research goals and objectives will be met, and how you plan to evaluate the methods used. Also discuss what precautions will be taken to minimize hazards to personnel, if necessary.

#### 8. LITERATURE CITED

A list of all publications cited in the Work Statement shall be included.

#### 9 COLLABORATIVE AND CONTRACTUAL ARRANGEMENTS

Copies of consortium, contractual and sub-contractual arrangements must be disclosed and copies of completed proposed agreements must be attached.

#### 10. LETTERS OF SUPPORT

Letter(s) in support of the proposal may be included.

#### 11. BIOGRAPHICAL SKETCHES

The biographical sketches of the Principal Investigator and main collaborators shall be included.

BE SURE TO CLEARLY LABEL EACH SECTION. NAME OF THE PRINCIPLE INVESTIGATOR AND TITLE OF EACH PROJECT SHOULD APPEAR AT THE TOP OF EACH PAGE. THE ENCLOSED WORK STATEMENT FORM MAY BE DUPLICATED FOR THE STATEMENT OF WORK.

# C. LICENSURE / CERTIFICATION REQUIREMENTS

1 Personnel: Not applicable

2. Facility: Not applicable

#### D. SPECIAL PROGRAM REQUIREMENTS:

The Commission does not fund research that uses human fetal tissue, cells or organs that are obtained from a living or dead embryo or fetus during or after an induced abortion. This restriction does not apply to research that uses human fetal tissue, cells or organs that are obtained from a spontaneous abortion or an ectopic pregnancy. ARS §§36.2302. (A).

Principal Investigator:	
Title of Project:	
	WORK STATEMENT

# SAMPLE LETTER OF ASSURANCE

NOTE: THIS LETTER OF ASSURANCE MUST BE ON INSTITUTION LETTERHEAD AND SIGNED BY A PERSON AUTHORIZED TO COMMIT THE INSTITUTION TO THESE ASSURANCE.

If a Contract is awarded, the **(FILL IN NAME OF INSTITUTION)** certifies that the price submitted was independently arrived out without collusion and agrees to:

- a. Comply with the Commission's monitoring activities.
- b. Comply with the Commission's auditing activities.
- c. Comply with the Commission's General Provisions.
- d. Provide services as required by the Work Statement of the Contract.
- e. Submit with the signed Contract, proof of insurance adequate to meet the stipulations of the General Provisions of the Contract.
- f. If applicable, submit with the signed Contract, documentation that the affiliated institution approved the use of human and/or animal subjects by its standing committee.

2.	Name of Principal Investigator:				
3.	Telephone Number of Principal Investigator:				
4.	Organizational Structure (select only one	type):			
	County Agency Educational Institution/District For-Profit Corporation Individual State Agency Municipality	Not-For-Profit Organization Partnership Sole Proprietorship Other (specify)			
5.	Institution's Federal Employer's Identific institution):	eation No. (or Social Security No. if you are not affiliated with any			
Signa	ature of Principal Investigator	Date			
	ature of Institution's Authorized Officer rating Approval of Proposal Submission	Date			
Туре	ed Name and Title				

Principal Investigator/Program Director (Last, first, middle):			
Provide the following information for	RAPHICAL SKETCH or the key personnel in the or h person. DO NOT EXCEED	rder listed for Form D FOUR PAGES.	Page 2
NAME	POSITION TITLE		
EDUCATION/TRAINING (Begin with baccalaureate or other initial	al professional advection, as	ioh oo numina, and	include
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
NOTE: The Biographical Sketch may not exceed the four-page limit. Follow the formats and instruction.  A. Positions and Honors. List in chronological order any honors. Include present membership on any limits and the sec	ctions on the attached previous positions, co	d sample. ncluding with vo	our present position. List
B. Selected peer-reviewed publications (in chrono preparation.	ological order). Do not	t include publica	ations submitted or in
C. Research Support. List selected ongoing or comp and non-federal support). Begin with the proj application. Briefly indicate the overall goals of t the research project. Do not list award amounts or	ects that are most r he projects and your i	elevant to the role (e.a. Pl. Co	research proposed in this
Biographi	cal Sketch Format Page		

Project	Title
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# **BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel in the order listed for Form Page 2.

ME	POSITION TITLE			
DUCATION/TRAINING (Begin with baccalaureate or other initial profes	ssional education, suc DEGREE (if applicable)	h as nursing, and include pos YEAR(s) FIELD	tdoctoral training.) OF STUDY	

Arizona Biomedic	al Researc	h Commis	ssion			Proposal No	o. FY 08-100
Request for C	Competi	tive Se	aled Proposals	ABRC ID#			
1. TITLE OF PROJECT							
2. Priority Area (A -	J):	] c	ategory: I				
3. Principal Investiga	ator (Last, Fir	st, Middle)		New Investigator [	No 🗌	Yes	
				3a. DEGREE(S)			
3b. POSITION TITLE				3c. MAILING ADDRE	SS (Street, c	ity, state, zip code)	
3e. DEPARTMENT, SER	RVICE, LABOR	ATORY, OF	REQUIVALENT				
3f. MAJOR SUBDIVISIO	N						
3g. TELEPHONE AND F	AX (Area code	e, number ar	nd extension)	E-MAIL ADDRESS:			
TEL:		FAX:					
4. HUMAN SUBJECTS RESEARCH	4a. Research If "Yes," Exem		☐ No ☐Yes	5. VERTEBRATE AN	NIMALS	No ☐ Yes	
☐ No ☐Yes	Yes  4b. Human Subjects Assurance No.			5a.lf "Yes," IACUC a	pproval Date	5b. Animal welfar  ☐ No	e assurance
6. DATES OF PROPOSUPPORT (month and		OF	7. TOTAL COSTS REQUES BUDGET PERIOD	TED FOR	\$	LI NO	
From	Through		7a. Year One (\$)	7b. Year Two (\$)		7c. Year Three (	\$)
8. APPLICANT ORGANI	ZATION			9. For ABRC Use Only	y		
Name							
Address							
10. ADMINISTRATIVE C	FFICIAL TO E	E NOTIFIED	D IF AWARD IS MADE	11. OFFICIAL SIGNIN	NG FOR APPL	ICANT ORGANIZ	ATION
Name				Name			
Address				Address			
E-Mail	TEL:		FAX:				
statements herein are true, of that any false, fictitious, or fra administrative penalties. I a project and to provide the red application.	complete and according to the comple	curate to the b nts or claims n responsibility eports if a con	R ASSURANCE: I certify that the test of my knowledge. I am aware nay subject me to criminal, civil, or for the scientific conduct of the tract is awarded as a result of this	"Per" or "For" signatu			DATE
<ol> <li>APPLICANT ORGANIZA statements herein are true, c the obligation to comply with a</li> </ol>	omplete and acc ABRC terms and that any false, fic	curate to the bactions if a ctitious, or frag	ACCEPTANCE: I certify that the lest of my knowledge, and accept a contract is awarded as a result of udulent statements or claims may e penalties.	ink. "Per" or "For" sign			DATE

14.	Have you ever been funded by ABRC before? If "Yes," list the fiscal years during which you were funded, the title of your proposal and describe what was accomplished:
15.	List other sources (external and internal) of funding for the proposed project, indicating the amounts and award periods for the other sources of funding:
16.	If your project represents a continuation of work previously funded by the ABRC, have you sought funding from national or other sources? Please elaborate:
1′	7. List other sources of funding being sought for this project, including the amount and award period being sought:

## **BUDGET INSTRUCTIONS**

#### 1 Personnel:

- A. Any principal investigator or co-principal investigator requesting salary must include appointment and salary verification letters.
- B. Tenure track faculty with a 12-month appointment may not apply for salary support form ABRC.
- C. Tenure track faculty with a 9-month appointment who do not have salary support from any other source for their summer salary may apply for a maximum of 2 months summer salary.
- D. Research track faculty may apply for a maximum of 4-months salary. Their salary from all sources cannot exceed the equivalent of a 11-month appointment. An individual with 9-months of salary support from other sources may apply for a maximum of 2 months of salary support from ABRC. Individuals with 7-months or less of salary support form other sources may apply for a maximum of 4-months salary from ABRC. Cost shifting to increase ABRC salary support is not permitted.
- E. Researchers in private institutions must follow the same rules when applying for salary support.
- 2. Consultant Costs: Itemize consultant fees, travel, etc.
- 3. Equipment: Itemize each major piece of equipment, or portion thereof. Request must not exceed 20% of the multi-year total budget. The title to equipment purchased through expenditure of funds from the Commission costing \$5,000 or more for a single item may revert to the ABRC at its sole discretion at the close of the contract. When requesting to purchase computer equipment or peripherals, please provide a complete description or bid for the components requested. ABRC may transfer the title of such Commission property to the Contractor's institution after it has been fully depreciated.
- 4. **Supplies**: Itemize by category. The Commission will not fund office cost or supplies (e.g., paper, copying costs, telephone costs, etc.). Non-expendable property having a useful shelf life of more than two years and an acquisition cost of \$5,000 or more per unit, must **not** be listed under supplies. Rather, such items must be listed under "Equipment."
- 5. Travel: The Commission will not fund out of state travel, travel to scientific meetings, or any other travel that is not directly related to completing the proposed research. All requests for travel must be justified as essential to the research outcomes.
- 6. Patient Care: Itemize these costs in the in-patient and out-patient categories.
- 7. Other Expenses: Itemize and describe the purpose of these expenses. Subscriptions to journals, membership dues to organizations or societies, purchase of books, and library search fee's or journal article copying cost, telephone cost, paper and other copying cost, etc. are not allowable. Also disallowed are tuition costs or laboratory fees for work leading to an academic degree. The Commission will allow a maximum of \$750 for manuscript preparation fees including page charges and illustration cost. Animal purchases and cost should be itemized here. If you are listing a subcontract total, please include a copy of the subcontract with your budget.
- 8. An itemized budget for each year of the proposal must be included.

Budget Forms (three pages) may be found at the end of the RFP.

# **BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD**

BUDGET CATEGORY TOTALS		INITIAL BUDGET PERIOD	ADDITIONAL YEARS OF SUPPORT REQUESTED				
			2nd	3rd			
PERSONNEL: Salary and fringe benefits. Applicant organization only.							
CONSULTAN	T COSTS						
EQUIPMENT							
SUPPLIES							
TRAVEL							
PATIENT	INPATIENT						
CARE COSTS	OUTPATIENT						
OTHER EXPE	ENSES						
SUBTOTAL D	IRECT COSTS					•	
CONSORTIUM							
CONTRACTUA COSTS	INDIRECT						
TOTAL DIRECT COSTS							
TOTAL INDIRECT COSTS							
TOTAL CO	ST						
TOTAL COS	STS FOR ENTIRE	E PROPOSED PROJEC	T PERIOD)				

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

DETAILED B	UDGET FOR ANN DIRECT COSTS		GET PERI	OD	FROM	Т	HROUGH
PERSONNEL (Applicant organiz	tation only)		% EFFORT		DOLLAR AMO	OUNT REQUES	STED (omit cents)
NAME	ROLE ON PROJECT	TYPE APPT. (months)	ON PROJECT	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	Principal						
	Investigator						
	1						
						)	
	SUBTOTALS	3					
CONSULTANT COSTS							
EQUIPMENT (Itemize)							
SUPPLIES (Itemize by category	· · · · · · · · · · · · · · · · · · ·						
TRAVEL					-		
PATIENT CARE COSTS	INPATIENT						
	OUTPATIENT						
OTHER EXPENSES (Itemize by	y category)						
SUBTOTAL DIRECT CO	STS FOR ANNIIA	L BUDGE	T PERIOD				6
SUBTOTAL INDIRECT							\$
COSTS	Indirect Cos	sts canno	t exceed 10	0% of Direc	t Cost.		
							•
TOTAL COSTS FOR AN		EKIOD (1	—————		ategory Limit.)		\$

# Project Title:

BUDGET JUSTIFICATION PAGE RESEARCH GRANT APPLICATION						
Initial Budget Period	Second Year of Support	Third Year of Support				
Total Costs Reques	ted for Entire Project Pe	riod		0		

RESOURCES
FACILITIES: Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under "Other," identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary.
Laboratory
Clinical:
Animal:
Computer:
Office:
Other:
IAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.
POON EQUIT MENT. List the most important equipment nems uneacy available for this project, noting the location and partition expansions of each

# **CHECK LIST**

The following check list is provided for your convenience. All required items must be submitted in the correct sequence in order for your proposal to be considered complete. Required forms are included in the RFP.

- 1. Request for Competitive Sealed Proposals 2 pages
- 2. Abstract form included
- 3. Lay Summary form included
- 4. Completed Work Statement form included
  - a. Multiple pages
  - b. Each section correctly identified
  - c. Each section beginning on a separate page
- 5. Completed Budget Worksheets
- 6. Letter of Assurance
- 7. Letters of Support if included
- 8. Biographical Sketch form included
- 9. Budget 3 pages forms included
- 10. Resources form included
- 11. General Provisions

- 12. One Original Proposal and Seven Copies
- 13. A List of Three Qualified Out of State Reviewers

# **GENERAL PROVISIONS FOR CONTRACTS**

#### 1. **DEFINITIONS**

As used throughout this document, the following terms shall have the meanings set forth:

- 1.1 "ABRC" means the Arizona Biomedical Research Commission.
- 1.2 "Bayh-Dole Act" means the provisions of 35 U.S.C. §§ 200 through 212 (as amended) together with all regulations promulgated thereunder.
- 1.3 "Budget Request" means those provisions of the Contract that describe the specific financial amounts, payment, accounting, and substantiation requirements and arrangements of the Contract.
  - "Chairman" means the Arizona Biomedical Research Commission (ABRC) Chairman or duly authorized representative.
- 1.5 "Commission" means the Arizona Biomedical Research Commission (ABRC) or any successor in interest.
- 1.6 "Contract" means all written documents comprising the agreement of the parties, including but not limited to, these General Provisions, the solicitation, the Contractor's proposal, the Acceptance Declination of Contract Award, Budget Requests, Budget Summaries, and budget transfer requests.
- 1.7 "Contract Material" means all written and electronic information, recordings, reports, findings, research information, abstracts, results, software, data, and any materials created, prepared, or received by the Contractor and Subcontractors in performance of this Contract.
  - "Contractor" means the person, firm, or organization performing, or accountable for performing the services or delivering the items described in this Contract.
- 1.9 "Controlling Party" means the party to this Contract that makes the largest verifiable direct payment of money to the research being performed hereunder together with Credit for Prior Related Research Payments unless otherwise agreed upon by both parties in writing. In the process of determining which party shall be the Controlling Party, the parties shall take into consideration which party is in the best position to perform the duties of the Controlling Party hereunder.
- 1.10 "Cost Reimbursement" provides for reimbursement to the Contractor for

## **GENERAL PROVISIONS FOR CONTRACTS**

actual costs incurred, as outlined in the Contract, in delivering services under the Contract.

- The phrase "Credit for Prior Related Research Payments" means cumulative 1.11 payments of money made by a party directly to a prior research project that leads to a Discovery made hereunder that the parties hereto mutually agree may be taken into account for purposes of determining the "Controlling Party." A party shall only be entitled to claim credit for prior related research payments if: (1) that party makes a written disclosure to the other party within ten (10) business days of receiving notification of contract award explaining the prior research and how it relates to the research conducted hereunder. (2) provides to the other party Verifiable evidence of direct payments of money to the prior research project, and (3) the other party agrees that the disclosing party is entitled to claim credit for payments of money paid by a party directly to a prior research project that leads to a discovery hereunder. If the parties agree that a party is entitled to claim Credit for Prior Related Research Payments, the claiming party may only claim credit for an amount mutually agreed upon by both parties.
- 1.12 "Derivative Work" means any work that is deduced or obtained from Contract Material or any portion thereof including, but not limited to any translation, arrangement, abridgment, recasting, transformation, or adaptation of Contract Material or any portion thereof.
- 1.13 "Development Costs" shall include only those Verifiable expenses arising solely and directly from the evaluation of a Discovery, registration of a Discovery, obtaining or protecting a patent covering a Discovery, marketing of a Discovery (including fees or commissions payable to a third party), negotiations of contracts with third parties for licenses to make use of a Discovery, attorneys' fees for obtaining a patent, attorney's fees for the negotiation and/or drafting of license agreements for a Discovery, and licensing of a Discovery.
- "Direct payment of money to the research being performed hereunder" means those payments of money made directly to the research being performed under this Contract solely for the purpose of completing that research and the term shall not include any indirect payments or administrative costs. In calculating a party's direct payment of money to the research being performed hereunder, the party may include amounts of salaries and benefits proportionate to the amount of time devoted by an employee directly to the research being performed hereunder, and funds that it receives from outside grants and other sources that the party pays directly to the research being performed under this Contract solely for the purpose of completing that research.

## **GENERAL PROVISIONS FOR CONTRACTS**

- 1.15 "Discovery" means any discovery, invention, or resulting patent(s) that arise(s), from research carried on by or under the direction of the Contractor in performance of this Contract.
- 1.16 "EDA" means effective date of Amendment.
- 1.17 "Executive Director" means the person designated to represent the Commission in the program administration of this Contract.
- 1.18 "Gross Income" means the total revenue received by the Controlling Party from the manufacture, use, lease, or sale of title to a Discovery or license to use thereof or any amounts attributable thereto, including the fair market value of any in-kind compensation.
- "Management Fees" means fees for expenses of maintenance of a Discovery and administrative costs arising from the accounting and reporting required under this Agreement. Management Fees shall be paid only from Net Income received after all Development Costs of both parties have been fully reimbursed. Management Fees shall not exceed ten percent (10%) of the Gross Income received.
- 1.20 "Net Income" means the Gross Income received by the Controlling Party less all Development Costs.
- 1.21 "Net Net Income" means the Gross Income received by Controlling Party less:
  - 1.21.1 All Development Costs;
  - 1.21.2 Management Fees; and
  - 1.21.3 All other amounts agreed to be excluded by prior written approval of both parties.
- 1.22 "Outside Funding" means all funding for the work to be conducted by the Principal Investigator under this Contract that does not come from the Contractor and shall include internal monetary awards from the Contractor over which the Principal Investigator has exclusive control.
- "Principal Investigator" means a person or entity who provides services or materials pursuant to the Contract in the nature of a developer, inventor, or researcher, usually requiring special skill and advanced education of a mental and intellectual nature. A Principal Investigator is usually a person who is an

## **GENERAL PROVISIONS FOR CONTRACTS**

employee or agent of the Contractor, but a Principal Investigator could also be an entity, the Contractor, or a Subcontractor. A Contract may involve more than one Principal Investigator.

- 1.24 "Professional acts" means services or acts of persons whose vocation or occupation requires special, usually advanced, education and skill which is predominantly mental or intellectual rather than physical or manual.
- "Reporting Period" means one of the two Reporting Periods during each calendar year. The first Reporting Period of the calendar year shall run from the first business day of each calendar year to the last business day in June. The second Reporting Period of each year shall run from the first business day in July to the last business day in December.
- 1.26 "Shall" means what is mandatory.
- 1.27 "State" means the State of Arizona including the Commission, and shall not, for purposes of this contract, include the Contractor.
- 1.28 "Subcontract" means any Contract between the Contractor and a third party to provide or be accountable for providing all or a specified part of the services or items which the Contractor has himself contracted with the Commission to provide.
- 1.29 "Verifiable" means evidenced by true and complete copies or originals of bills, invoices or the like and similar evidence of payments of such bills, invoices or the like.
- "Work Statement" means those provisions of this Contract which delineate the scope and manner of the specific services to be performed and/or describe the items to be supplied in the performance of this Contract. If the provisions of the Work Statement conflict with the General Provisions, the terms of the Work Statement shall govern.

#### 2. GENERAL REQUIREMENTS

- 2.1 The Contractor shall not bill costs to the Commission until the contract is effective. The Contractor may, at the Contractor's own risk, incur allowable expenditures as of July 1 following the Commission's determination to award or extend the Contract until the contract or renewal is fully executed or becomes effective.
- 2.2 This Contract, and any amendments thereto, shall become effective on the

## GENERAL PROVISIONS FOR CONTRACTS

date executed by the parties or at a later date as specified (t)herein.

- 2.3 The Contractor, unless otherwise exempt by law, shall obtain and maintain all licenses, permits and authority necessary to do business and render services under this Contract.
- 2.4 The parties hereto agree that the Contractor is an independent Contractor in the performance of this Contract and is not an officer, employee or agent of the Commission.
- 2.5 Except for persons employed by the Arizona Board of Regents, or units thereof, no individual employed by the State shall have a substantial interest in this Contract or receive a substantial benefit that may arise therefrom.
- 2.6 Contractors receiving State funds under this Contract shall comply with the certified financial and compliance audit provisions of A.R.S. §35-181.03.

#### 3. OTHER CONTRACTS

The Commission may perform additional work related to this Contract or award other Contracts for such work. The Contractor shall cooperate reasonably with such other Contractors and/or State employees in scheduling and coordinating its work with such additional work. The Contractor shall afford other Contractors reasonable opportunity for the execution of their work and shall not commit or permit any act which will unreasonably interfere with the performance of work by any other Contractor or by State employees. The terms of this Contract shall be included in all Subcontracts as well as Contracts with other Contractors. The Commission shall equitably enforce this Section as to all Contractors to prevent unreasonably burdening any Contractor.

#### 4. SUBCONTRACTS AND ASSIGNMENTS

- 4.1 The Contractor shall not subcontract with any other person or entity to provide or account for any service or item required by this Contract unless it is permitted in the Contract or the Commission has provided the Contractor with prior written approval.
- 4.2 If Subcontracts are permitted hereunder, the Contractor agrees to use written Subcontracts which conform to Federal and State laws and regulations appropriate to the service or activity covered by the Subcontract, and which include the terms of this Contract.
- 4.3 The Contractor agrees that the provisions of this Contract shall be included

#### GENERAL PROVISIONS FOR CONTRACTS

in and apply to all Subcontracts as if the Subcontractor were the Contractor referred to herein. The Contractor is responsible for Contract performance without regard to whether Subcontractors are used.

- 4.4 The Contractor shall submit a complete copy of each proposed Subcontract with all attachments and proposed amendments to the Commission for its prior approval. Upon approval by the Commission and the execution of the Subcontract, the Contractor shall submit a complete copy of each Subcontract with all attachments to the Executive Director within fifteen (15) business days of its effective date.
- 4.5 The Contractor's rights or obligations under this Contract shall not be assigned without the prior written consent of the Commission. It shall be deemed to be a assignment without approval if, without the prior written approval of the Commission: (i) more than fifty percent (50%) of the voting control of the Contractor has been or will be transferred to third parties within a twelve (12) month period or (ii) more than fifty percent (50%) of the equity ownership in the Contractor has been or will be transferred to third parties within a twelve (12) month period.
- 4.6 The Contractor and all subcontractors shall agree that if, at anytime while this Contract is in effect, they or any one of them acquire or have acquired patents, rights, or interests in a patent that dominates over a Discovery that arises under this Contract, the Contractor or subcontractor that so acquired or acquires will notify the Commission within thirty (30) days of learning of a dominating patent and will cooperate fully with the Commission if it so requests in order to protect any interest in or with respect to the Discovery that belongs to or is to be received, in whole or in part, by the Commission pursuant to the Contract.

#### 5. OWNERSHIP OF INTELLECTUAL PROPERTY

- It is the intent of the Commission that all intellectual property developed under this Contract be used and controlled in ways to produce the greatest benefit to the parties to this Contract, the inventor, the inventor's parent institution, and the citizens of the State of Arizona.
- 5.2 Copyrights and Research Information
  - 5.2.1 Title and exclusive copyright to all Contract Material shall vest solely in the Controlling Party. Each party to this Contract shall execute all documentation requested by the Controlling Party for the purpose of securing for the Controlling Party all interests in and to all copyrights

#### **GENERAL PROVISIONS FOR CONTRACTS**

to the Contract Material.

- 5.2.2 Each party to this Contract that is not the Controlling Party shall have full, complete, perpetual, irrevocable and nontransferable rights to reproduce, duplicate, adapt, make Derivative Works, distribute, display, disclose, publish, and otherwise use all Contract Material. The Controlling Party may, at its option, and in its sole discretion, hold, sell, or otherwise dispose of its title or any lesser right or interest to any Contract Material. If the Controlling Party declines to take title to the Contract Material or desires to transfer title of the Contract Material to a third party, the other party to this Contract shall have the first right of refusal to take title to that Contract Material and act as the Controlling Party hereunder.
- 5.2.3 Prior to any publication, the Contractor shall notify the Commission of the date, time and location of any planned publication and forward to the Commission a copy of any Contract Material or Derivative Works including, but not limited to, manuscripts, abstracts, presentations, illustrations, tables, and photographs accepted for publication prior to the publication release date. Contract Material that contains proprietary or confidential information, sent to the Commission for review, shall be kept confidential to the extent permitted by law. Neither party shall release confidential information to the public without the prior express written permission of the other or pursuant to subpoena or court order.
- 5.2.4 Unless otherwise required by law, neither party shall release draft, interim, incomplete, or unfinished Contract Material to the public received from, or concerning any ongoing research project.
- 5.2.5 The Contractor shall give recognition to the Commission for its support of the research project when publishing Contract Material, Derivative Work, or releasing research project related public information.

## 5.3 Discoveries

5.3.1 Except as provided in section 5.7 below, title to and the exclusive right to patent any Discovery resulting from research carried on by or under the direction of the Contractor in performance of this Contract shall vest solely in the Controlling Party. Each party to this Contract shall execute all documentation requested by the Controlling Party for the purpose of securing for the Controlling Party all rights

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(including but not limited to the right to patent), titles, and interests in and to such Discovery. If the Controlling Party declines to take title or desires to transfer title of the Discovery to a third party, the other party to this Contract shall have the first right of refusal to take title to that Discovery and act as the Controlling Party hereunder.

- 5.3.2 Each party to this Contract that is not the Controlling Party shall have full, complete, perpetual, irrevocable, and nontransferable rights to duplicate, produce, and otherwise use any Discovery. The Controlling Party may, at its option, and in its sole discretion, hold, sell, or otherwise dispose of its title or any lesser right or interest to any Discovery. No less than ten (10) business days prior to any transfer of title or any lesser interest in a Discovery, the Controlling Party shall notify all other parties of the proposed transfer and provide copies of the operative transfer documents to the other parties. The Controlling Party may evaluate, patent, or license any Discovery using its own resources or may make an agreement with the other party to this Contract, third party, or patent management organizations to undertake such activities.
- 5.3.3 The Contractor shall require each Principal Investigator and other persons involved in the research hereunder to promptly disclose all Discoveries made hereunder to a designated Contractor representative. Within thirty (30) days of receiving a disclosure and supporting documentation, the Contractor representative shall promptly transmit a copy of the disclosure to the Commission. Within 45 days of the Commission's receipt of the disclosure, the parties shall mutually determine which party shall be the Controlling Party.
- 5.3.4 The Controlling Party will direct that title to or interest in a Discovery be one or more of the following:
  - 5.3.4.1 transferred, licensed, or assigned outright to the discoverer or inventor.
  - 5.3.4.2 assigned to one or more institutions or patent management organizations for patent and/or commercial development;
  - 5.3.4.3 evaluated for commercial potential by a third party;
  - 5.3.4.4 licensed or assigned to any other party to this Contract for patent management or development and

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subsequently licensed or assigned to any other person or entity for commercialization; or

5.3.4.5 patented by the Controlling Party and then licensed or assigned to any other person or entity for commercialization.

The Controlling Party shall not grant or sell a license or any other interest in a Discovery unless the other party to this Agreement has given its prior written consent to the grant or sale.

- 5.4 Within forty-five (45) days of receipt of any Gross Income from the sale, transfer, or licensing of any Contract Material or any copyright thereto or any Discovery or patent thereto, the Controlling Party shall reimburse each party their respective Discovery Costs, Management Fees, and distribute their shares of the Net Net Income as described in section 5.5 below.
- 5.5 For sections 5.2 and 5.3, within forty-five (45) days of the receipt of Gross Income, the Controlling Party shall distribute the Gross Income in the following order and in accord with the following:

The Controlling Party shall reimburse each party to this Agreement for all accrued Development Costs. The Controlling Party shall distribute reimbursements of Development Costs between itself, and all other parties to the extent possible. If sufficient funds are not available to pay all Development Costs in full, the Gross Income shall be distributed pro rata to each party. Before paying any Management Fees or distributing any Net Net Income, the Controlling Party shall first pay all accrued Development Costs of all parties.

5.5.2 The Controlling Party may, at its discretion, take a Management Fee not to exceed ten percent (10%) of the Gross Income received. The Controlling Party shall distribute Management Fees to the Controlling Party. The Management Fees distributed to the Controlling Party shall not exceed ten percent (10%) of the Gross Income. Management Fees shall be reimbursed only after all of the accrued Development Costs of all parties have been reimbursed in full. The Commission may adopt a percentage Management Fee equal to that elected by the Contractor or taken by the Contractor acting as Controlling Party on other projects.

The Controlling Party shall pay all of the Net Net Income equally to

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each party unless the parties agree otherwise in writing. Net Net Income may be distributed only after all of the accrued Development Costs of all parties have been fully reimbursed and the applicable Management Fees have been paid.

- Within thirty (30) days after the end of each Reporting Period, the Controlling Party shall account to each party in writing for all Gross Income received during that Reporting Period and all distributions therefrom. At that same time, each party to this Agreement shall report to the other all outstanding Development Costs that it has incurred under this Agreement.
- If the Bayh-Dole Act applies to a Discovery made hereunder, and the 5.7 Commission would otherwise be the Controlling Party hereunder, the party that is the "contractor" under the Bayh-Dole Act shall have title to the Discovery. Within sixty (60) days of the Commission's receipt of written notice in section 5.3.3, the Commission may make written request for and the Contractor shall make an application to the Federal funding agency and/or the United States Department of Commerce as provided in the Bayh-Dole Act for permission to transfer the title to such Discovery or resulting patent to the Commission. The Commission shall approve the form of the application before it is submitted. The Commission shall be informed promptly of any subsequent communications with the Federal funding agency and/or the United States Department of Commerce regarding the request. If the Federal funding agency and/or the United States Department of Commerce does not grant permission for the transfer: (1) the Commission shall, nevertheless, have the rights to its share of Gross Income as described in 5.5, and (2) the Contractor shall then assume the responsibilities and authorities of the Controlling Party or license the Discovery to the Commission for purposes of commercial development. In all circumstances, and without regard to whether the Commission has requested the transfer of title or patent rights or whether the Federal funding agency and/or the United States Department of Commerce has approved any such transfer, the Commission shall retain its right to share in the distribution of Gross Income as described in section 5.5 above.
- In the event that a share of Net Net Income is received by the Commission pursuant to section 5.5, a portion of that share of Net Net Income received by the Commission shall be paid to the individual(s) who created that intellectual property as additional consideration for his, her, or their creative efforts. This portion is to be determined by the Commission considering individual institutional policy, recommendations from patent management organizations or any other knowledgeable source, and other relevant factors. In no event will the inventor or inventors collectively, be awarded less than

# GENERAL PROVISIONS FOR CONTRACTS

25% of the share of Net Net Income provided to the Commission.

#### 6. **CONFIDENTIALITY**

- 6.1 The Contractor, its Principal Investigators, employees, and authorized agents engaged in work under this Agreement may present at symposia or professional meetings and publish in journals, theses or dissertations, or otherwise of their own choosing, methods and Contract Material. The Contractor agrees to submit manuscripts of proposed publications to the Commission and all other parties prior to publication for review to ascertain that no confidential or proprietary information has been inadvertently disclosed by the proposed manuscript. The Contractor shall delay publication for no less than thirty (30) days to allow the parties to review the manuscript. If the parties determine that confidential or proprietary information may be disclosed, the Contractor shall further delay publication for a time period necessary to allow the parties to protect their interests.
- 6.2 Except as provided in Sections 5.2.3 and 6.1, the Contractor shall not disclose any Contract Material any third party without the Commission's prior written consent, which shall not be unreasonably withheld.
- 6.3 To accomplish the work under this Agreement, the Commission may disclose information to the Contractor that it considers confidential The Commission agrees to disclose only information necessary to the work and to clearly mark as "Confidential Information" any information it considers confidential. The Commission will send Confidential Information in writing only to the Principal Investigator or orally disclose it to the Principal Investigator and reduce it to writing within thirty (30) days of disclosure. The Contractor and the Principal Investigator agree, to the extent permitted by law, that Confidential Information will remain the property of the Commission and, for 5 years from the end of this Agreement, Confidential Information will not be used or disclosed to others except in furtherance of this Agreement. This obligation of non-use and non-disclosure will not apply to any portion of the Confidential Information that: (1) was known to the Principal Investigator before disclosure by ABRC; (2) is disclosed to the Principal Investigator by a third party; or (3) is or becomes known to the public through no fault of the Principal Investigator.

#### 7. CONFIDENTIALITY OF MEDICAL RECORDS

The Contractor shall establish and maintain written procedures and controls that (ABRC RFP 08-100)

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comply with Arizona Administrative Code ("A.A.C.") R9-1-311 through R9-1-315 regarding disclosure of confidential medical information and records. Upon Commission approval of Contractor's written procedures governing confidentiality, the Contractor may release information pursuant to its approved procedures. In the absence of approved procedures, requests for medical information shall be in writing and disclosure authorized by the Commission, or where permitted by the rules, by the director of a local health department. No medical information contained in Contractor's records or obtained from the Commission or from others in carrying out its functions under this Contract shall be used or disclosed by Contractor, its agents, officers, employees or Subcontractors except as is essential to the performance of duties under this Contract or otherwise permitted under the statutes and rules of the Commission. Disclosure to the Commission is deemed essential to the performance of duties under this Contract. Medical information, names, or other information regarding any person applying for, claiming, or receiving items or services contemplated in this Contract, or any employer of such person shall not be made available for any political or commercial purpose. Information received from a Federal or State agency or from any person or provider acting under the Federal or State agency pursuant to Federal or State law, shall be disclosed only as provided by Federal or State law.

#### 8. RECORDS

Contractors who submit cost or pricing data as provided in A.R.S. §41-2543 shall maintain books and records which reflect that cost or pricing data under the Contract and shall reflect the Contract services and expenditures. All books and records shall be maintained in accordance with Generally Accepted Accounting Principles (GAAP).

## Contractor further agrees:

- 8.2.1 To submit all reports and invoices as specified in the Work Statement of this Contract.
- 8.2.2 The Contractor and any Subcontractors shall preserve and make available to the Commission and its auditors all records for a period of five (5) years from the date of final payment under this Contract and for such period as is required by any other paragraph of this Contract including the following:
  - 8.2.2.1 If this Contract is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of five (5) years from the date of any such termination.

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- 8.2.2.2 Records that relate to disputes, litigations or the settlement of claims arising out of the performance of this Contract or to cost and expenses of this Contract to which exception has been taken by the Executive Director shall be retained by the Contractor until such appeals, litigations, claims or exceptions have been finally resolved.
- 8.2.2.3 If requested, the Contractor shall submit such records relating to the Contract to the address specified by the Executive Director.

## 9. INDEMNIFICATION AND INSURANCE

9.1 Unless the Contractor is insured pursuant to A.R.S. §§ 41-621, et seq., the Contractor shall at all times indemnify, defend and save harmless the Commission and/or any of its agents, officials and employees from any and all claims, demands, suits, actions, proceedings, loss, cost and/or damages of every kind and description including any attorney's fees and/or litigation expenses brought or made against or incurred by the Commission on account of loss of or damage to any property or for injuries to or death of any person, caused by, arising out of, or contributed to, in whole or in part, by reasons of any act, omission, professional error, fault, mistake, or negligence of the Contractor, its employees, agents, representatives, or Subcontractors, their employees, agents, or representatives in connection with or incident to the performance of this contract or arising out of Worker's Compensation claims, Unemployment Compensation claims, or Unemployment Disability Compensation claims of employees of the Contractor and/or its Subcontractors or claims under similar such laws or obligations. The Contractor's obligation under this paragraph shall not extend to any liability caused by the sole negligence of the Commission or its employees.

The Contractor shall comply with all laws regarding unemployment insurance and worker's compensation.

The Contractor shall provide and maintain and/or cause its Subcontractors to provide and maintain liability insurance as described below or liability coverage from the Arizona Department of Administration Risk Management Division. In no event shall the total coverage be less than the minimum insurance coverage specified below:

9.3.1 Comprehensive general liability insurance with a minimum combined

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single limit of two million dollars (\$2,000,000) each occurrence. The policy shall include coverage for bodily injury, broad form property damage, (including completed operations), personal injury (including coverage of Contractual and employee acts), blanket Contractual, Contractor's protective, sudden and accidental pollution, products and completed operations.

- 9.3.2 Comprehensive automobile liability insurance with a combined single limit for bodily injury and property damage of not less than two million dollars (\$2,000,000) each occurrence with respect to Contractor's vehicles (whether owned, hired, non-owned), assigned to or utilized in the performance of this Contract.
- 9.3.3 Professional liability insurance with a minimum combined single limit of two million dollars (\$2,000,000) for each occurrence if professional acts shall be required in the performance of this Contract.
- 9.4 The Contractor shall name the State of Arizona, its agents, officials and employees as additional insureds and shall specify that the insurance afforded by the Contractor shall be primary insurance and any insurance or self-insurance of the State, the Commission or its employees shall be excess, not contributory insurance, to that provided by the Contractor. Said policy shall contain a severability of interests provision. Such policy(ies) shall contain a requirement that the insurer notify the Commission promptly of any change in coverage terms or amounts, in advance of a lapse or cancellation of coverage, or of failure to pay premium when due.
- 9.5 Contractor's failure to procure and maintain the required liability insurance or to provide proof thereof to the Commission within thirty (30) days following the commencement of a new policy period, shall constitute a material breach of the Contract upon which the Commission may immediately terminate this Contract. Prior to the effective date of this Contract, the Contractor shall furnish the Commission with copies of the State of Arizona Certificate of Insurance (RM7200.1) drawn in conformity with the above insurance requirements. The State of Arizona reserves the right to request and receive certified copies of any or all of the above policies and/or endorsements.

#### 10. CERTIFICATIONS

The Contractor certifies that all services shall be performed in conformity with the requirements of this Contract and by qualified personnel in accordance with generally recognized standards in the biomedical research community and industry.

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#### 11. AMENDMENTS

- 11.1 No condition, requirement or alteration contained in or made a part of this Contract shall be waived or modified without an approved, written amendment to this Contract. Amendments shall be effective only if in writing and signed by all parties.
- 11.2 Any request for an amendment shall be in writing, shall be delivered in person, courier or U.S. mail and shall be directed to the persons and addresses specified herein.

#### 12. DISPUTES

- 12.1 In the event of a dispute under this Contract, the parties agree to make a good faith attempt to resolve the dispute prior to taking formal action.
- 12.2 If the dispute cannot be resolved pursuant to Subsection 12.1 above, the dispute shall be resolved in an administrative hearing pursuant to A.R.S.§ 41-2615 and A.A.C. R2-7-901, et seq.
- 12.3 This Contract shall be construed in accordance with Arizona law and any legal action thereupon shall be initiated in the State of Arizona.

#### 13. TERMINATION OF CONTRACT

The Commission, the State or Contractor may terminate this Contract under the following conditions:

- 13.1 The Commission, in addition to other rights set forth elsewhere in the Contract, may terminate this Contract in whole or in part without cause effective thirty (30) days after mailing written notice of termination by certified mail, return receipt requested to the Contractor.
  - 13.1.1 In the event of termination as provided in this Section, the Contractor shall stop all work as specified in the notice of termination and immediately notify all Subcontractors in writing to do the same.
  - 13.1.2 The Contractor shall be paid the Contract price for all services and items completed up to the date of termination. In addition, the Contractor will be paid its reasonable actual costs for work in progress as determined by GAAP up to the date of termination. Upon such termination, the Contractor shall deliver to the Commission a

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complete set of all documents, programs and other information prepared in performance of the Contract.

- The Commission may terminate this Contract in whole or in part if, during the term of this Contract, the Contractor is listed on the Master List of debarments, suspensions and voluntary exclusions maintained pursuant to A.A.C. R2-7-933. In such case, the Executive Director shall transmit written notice of termination to the Contractor by certified mail, return receipt requested, and this Contract shall be terminated effective upon receipt thereof by the Contractor or such later date as is specified in the notice. In the event the Executive Director terminates this Contract in whole or in part as provided in this Subsection, all subsections of this Section 13 are incorporated into this Subsection by reference and shall apply to the same extent as if expressly set out herein.
- 13.3 The Commission may terminate this Contract by written notice to the Contractor if it is found by the Executive Director after notice and opportunity for a hearing that gratuities in the form of entertainment, gifts, or otherwise were offered or given by the Contractor or any agent or representative of the Contractor to any officer or employee of the State with a view toward securing a Contract or securing favorable treatment with respect to the awarding or amending or the making of any determinations with respect to the performing of such Contract.
- Pursuant to A.R.S. §38-511 the Commission or any other agency of the State 13.4 may, within three (3) years after its execution, cancel this Contract without penalty or further obligation by the Commission or such other State agency if any person significantly involved in initiating, negotiating, securing, drafting or creating this Contract on behalf of the Commission or such other State agency is, at any time while the Contract or any extension of the Contract is in effect, an employee or agent of any other party to the Contract in any capacity or a consultant to any other party of the Contract with respect to the subject matter of the Contract. Cancellation under this subsection shall be effective when written notice from the Commission or such other State agency is received by all other parties to the Contract unless the notice specifies a later time. In addition to the right to cancel this Contract as provided in this Subsection, the Commission or such other State agency may recoup any fee or commission paid or due to any person significantly involved in initiating, negotiating, securing, drafting or creating this Contract on behalf of the Commission or such other State agency from any other party to this Contract arising as the result of this Contract.
- 13.5 This Contract may be terminated by mutual written agreement of the parties

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specifying the termination date therein.

- 13.6 If monies are not appropriated or otherwise made available to support continuation of performance in a subsequent fiscal period, the contract shall be canceled without any further obligation upon the Commission or State.
- 13.7 The Commission may, at any time, by written order to the Contractor, require the Contractor to stop all or any part of the work called for by this Contract for a period of ninety (90) calendar days after the order is delivered to the Contractor. The order shall be specifically identified as a stop work order issued under this clause. Upon receipt of a stop work order, the Contractor shall immediately cease all work being performed hereunder and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the stop work order during the period of work suspension. The Commission may, in its sole discretion, extend for ninety (90) days the term of or cancel a stop work order at any time. If the Commission cancels a stop work order or the period of a stop work order or any extension thereof expires, the Contractor shall promptly resume work. If the Commission issues a stop work order, the Commission shall make an equitable adjustment in the performance schedule and the Contract shall be amended accordingly.

#### 14. DEFAULT

- 14.1 The Commission, in addition to other rights set forth elsewhere in the Contract, may by written notice of default require that the Contractor cure any default within a period of time specified by the Commission in the notice of default. Upon receipt of a notice of default, the Contractor shall promptly send written acknowledgment of receipt of the notice of default to the Commission. If the Contractor fails to cure the default within the time period specified in the notice of default, the Commission may terminate this Contract in whole or in part if the Commission determines that the Contractor has failed to perform any requirement.
- 14.2 The Contractor shall continue the performance of this Contract to the extent not terminated.
- 14.3 In the event the Commission terminates this Contract in whole or in part as provided in this Section, the Commission may procure, upon such terms and in such manner as deemed appropriate, services similar to those so terminated, and unless the Contractor is a governmental agency, instrumentality or subdivision thereof, or Indian tribe, it shall be liable to the Commission for any excess costs incurred by the Commission in obtaining such similar services.

### **GENERAL PROVISIONS FOR CONTRACTS**

- 14.4 Except with respect to defaults of Subcontractors, the Contractor shall not be liable for any excess costs if the failure to perform the Contract arises out of causes, natural and unnatural, that are unanticipated and beyond the control and which occur without the fault or negligence of the Contractor. Such causes may include, but are not restricted to, acts of God or of the public enemy, acts of the State or Federal Government in either their sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, freight embargoes, unusually severe weather, unanticipated loss of personnel, unanticipated changes in availability of patient populations, and unanticipated equipment malfunctions. If the failure to perform is caused by the default of Subcontractor, and if such default arises out of causes beyond the control of both the Contractor and Subcontractor and without the fault or negligence of either, the Contractor shall not be liable for any excess costs for failure to perform, unless the services to be furnished by the Subcontractor were obtainable from other sources in sufficient time to permit the Contractor to meet the required delivery schedule.
- 14.5 If this Contract is terminated as provided herein, the Commission, in addition to any other rights provided in this Section, may require the Contractor to transfer title to and deliver to the Commission or its successor or assigns, in the manner and to the extent directed by the Commission, such partially completed reports or other documentation as the Contractor has specifically produced or specifically acquired for the performance of such part of the Contract as has been terminated consistent with Section 5 herein. Payments for completed reports and other documentation delivered to and accepted by the Commission shall be at the Contract price. Payment for partially completed reports and other documentation delivered to and accepted by the Commission shall be in an amount agreed upon by the Contractor and the Commission.
- 14.7 The rights and remedies of the Commission enumerated in this Section shall be in addition to any other rights and remedies provided by or under this Contract by law.

#### 15. NON-DISCRIMINATION

The Contractor shall comply with State Executive Order No. 99-4 and A.R.S. §§41-1461 et seq., which mandate that all persons, regardless of race, color, religion, sex, age, national origin or political affiliation, shall have equal access to employment opportunities. The Contractor shall comply with all other applicable federal and state employment laws, rules and regulations, including the Americans with

### GENERAL PROVISIONS FOR CONTRACTS

Disabilities Act. The Contractor shall take affirmative action to ensure that applicants for employment and employees are not discriminated against due to race, creed, color, religion, sex, national origin or disability.

#### 16. ASSIGNMENT OF OVERCHARGES

The Contractor, the Commission and the State recognize that in actual economic practice overcharges resulting from antitrust violations are in fact borne by the purchaser. Therefore, the Contractor hereby assigns to the Commission and the State any and all claims for such overcharges.

#### 17. CONTRACT PAYMENTS

- 17.1 Payments made by the Commission to the Contractor pursuant to this Contract are conditioned upon the availability to the Commission of funds authorized for expenditure in the manner and for the purpose herein. The Commission shall not be liable for any purchases or Subcontracts entered into by the Contractor in anticipation of such funding.
- 17.2 Payments made by the Commission to the Contractor are conditioned upon receipt of applicable, accurate and complete reports to be submitted by the Contractor. The Commission will pay the Contractor within sixty (60) days of receipt of complete reports.
- 17.3 If the Contractor is in any manner in default in the performance of any obligation under this Contract, or if audit exceptions are identified, the Commission may, at its option and in addition to other available remedies, either adjust the amount of payment or withhold payment until satisfactory resolution of the default or exception. The Contractor shall have the right to written notice of the Commission's action in adjusting the amount of payment or withholding payment. Under no circumstances shall the Commission authorize payments to the Contractor that exceed an amount specified in the Contract without an approved written amendment to the Contract. The Commission may, at its option, withhold payments or terminate the contract for failure to file required reports or until all final reports and deliverables are received.
- 17.4 Contractor shall not have discretion under this Contract to carry-over funds or services delivery from one state fiscal year to a subsequent state fiscal year. Contract continuation is subject to the following conditions:

17.4.1 Availability of funds; and

# GENERAL PROVISIONS FOR CONTRACTS

- 17.4.2 Demonstration of sufficient progress toward Contract goals and objectives of the research as set forth in the Proposal or Work Statement: and
- 17.4.3 Work Statement and Contract rates negotiated and agreed to by both parties.
- 17.5 Under any extension of work authorized under section 14.4, the Contractor shall submit all revised requests for payment during the extension period.
- 17.6 The Commission will not authorize a revised expenditure report unless the Contractor has submitted such report to the Commission on or before June 1 of the year following the year to which the revision applies.

### 18. RECOUPMENT OF CONTRACT PAYMENTS

18.1 Unacceptable Expenditures

The Contractor shall reimburse the Commission for all Contract funds expended which are determined by the Commission or the Auditor General not to have been disbursed by the Contractor in accordance with the terms of this Contract.

#### 18.2 Contracted Services

- 18.2.1 If the services to be performed as described in this Contract are materially less than one hundred percent (100%) of the services required hereunder, funds to be returned to the Commission will be determined by multiplying the unit of service cost as listed in the Budget Requests by the number of services which are below the one hundred percent (100%) requirement.
- 18.2.2 If the number of services provided in any service name is less than the services for which the Contractor received compensation, funds to be returned to the Commission shall be determined by multiplying the unit of service cost as listed in the Budget Requests by the number of services Contractor did not provide during the budget term.

#### 18.3 Refunds

The Contractor shall, within forty-five (45) days of termination, refund the greater of the amount refundable in accordance with Subsection 17.2 hereof (Contracted Services).

### GENERAL PROVISIONS FOR CONTRACTS

#### 19. MANAGEMENT OF FUNDS

For all Contracts, the practices, procedures and standards specified in and required by the Accounting and Auditing Procedures Manual for Arizona Department of Administration Funded Programs shall be used by the Contractor in the management of Contract funds and by the Commission when performing a Contract audit. Funds collected by the Contractor in the form of fees, donations and/or charges for the delivery of these Contract services shall be accounted for in a separate fund.

#### 20. ALLOWABLE EXPENDITURES

Expenditure of funds advanced, or qualifying for reimbursement, pursuant to this Contract shall be made by the Contractor only for the following:

Services or material approved or appropriated for, and used in, the performance of services herein agreed to be provided.

Services or materials which are received by the Contractor:

- 20.2.1 During the Contract term for which the funds are made available; and
- 20.2.2 On or after the effective date of the Contract or, with regard to funds made available during a Contract term by an amendment to the Contract, on or after the effective date of that amendment; and
- 20.2.3 On or before the termination date.
- 20.3 Dollar amounts approved in the account classifications shown on the annual Budget Summary Page of this contract may be adjusted within ten percent (10%) of the original amount shown provided that the total amount of the contract shown on the Budget Summary Page remains unchanged. Adjustments shall be made in accordance with the following:
  - 20.3.1 The Contractor and Principal Investigator may reassign funds within the personnel category without requesting a change in writing so long as personnel are not being added or replaced. If key personnel are being added or replaced, the request must be made in writing. Approval by the Executive Director of the requested change constitutes a contract amendment.
  - 20.3.2 The salary limits for Principal Investigators shall not be exceeded.

#### **GENERAL PROVISIONS FOR CONTRACTS**

- 20.3.3 The Contractor and Principal Investigator may reassign funds without restriction from one category to another among all other categories in which funds have been approved except Personnel and Equipment. In order to reassign funds from Personnel or Equipment to any other category or reassign funds from any other category to Personnel or Equipment, the Contractor must make a written request to the Executive Director for such reassignment and the Executive Director must approve the request in writing
- 20.3.4 The Contractor shall submit a written request to the Commission for approval before the Contractor may reassign funds to a category in which no funds were approved in the annual Budget Request.

#### 21. VISITATION AND INSPECTION

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- 21.1 The Contractor agrees that the Commission and any other appropriate agent of the State or Federal Government, or any of their duly authorized representatives, shall have access during reasonable hours to the Contractor's facilities and the right to examine Contractor's books, documents and records involving transactions related to this Contract.
- 21.2 The Contractor further agrees to include in any Subcontracts relating to this Contract a provision to the effect that the Subcontractor agrees that the Commission and any other appropriate agent of the State or Federal Government, or any of their duly authorized representatives, shall have access to the Subcontractor's facilities and the right to examine any books, documents and records of the Subcontractor, involving transactions related to the Subcontract and that such books, documents and records shall not be disposed of except as provided herein.

#### 22. EQUIPMENT

22.1 The title to equipment purchased through expenditure of funds from the Commission costing \$5000 or less for a single item or equipment having a shelf life of 2 years or less will remain with the Contractor. The title to equipment purchased through expenditure of funds from the Commission costing in excess of \$5000 or having a shelf life of more than 2 years, for a single item shall remain the property of the Commission unless the Commission, in its sole discretion, agrees to transfer title to the Contractor. The final disposition of all Commission property shall be determined by the Commission in accordance with applicable statutes and rules relating to State Materials Management.

# **GENERAL PROVISIONS FOR CONTRACTS**

- 22.2 The Contractor agrees to exercise reasonable control over all equipment purchased with capital outlay expense of Contract funds. All Commission equipment lost, stolen, rendered unusable or no longer required for research project operation must be reported immediately to the Commission for disposition instructions. The Contractor shall conduct a physical inventory of Commission equipment, using forms supplied by the Commission, within sixty (60) days after the end of the Contract.
- 22.3 Requests for purchases of capital equipment which were not part of the original budget must be submitted prior to the third quarter of the Contract for all one year Contract awards. The same restriction applies to the final year of multi-year Contract awards. All new requests for purchases of capital equipment must be requested and justified in writing and require the written approval of the Executive Director.
- 22.4 Expenditures submitted for maintenance and/or repairs of equipment necessary to the research may be reimbursed upon approval by the Commission. Upon prior written approval maintenance agreements may be purchased for new equipment acquired under this contract. Maintenance agreements may only be purchased for the duration of the contract under which the equipment was acquired or is to be used. Requests for approval must be made in the Annual Budget Summary or in a Budget Transfer Request.

#### 23. INFRINGEMENT OF PATENTS AND COPYRIGHTS

- 23.1 Unless the contractor is an agency insured pursuant to A.R.S. § 41-621, et seq., the Contractor, at his/her sole expense, shall defend any claim, action, or suit which may be brought against the Commission for the infringement of United States patents or copyrights arising from the Contractor's use of any equipment, materials, or information prepared or developed in connection with performance of this Contract. In any such claim, action, or suit the Contractor shall satisfy any final judgment for such infringement. The Commission shall give the Contractor written notice of such claim, action, or suit together with full information. The Commission shall cooperate with the Contractor with regard to any claim, action, or suit. The Commission, acting in its sole discretion may participate in the defense of any such claim, action, or suit if principles of governmental or public law are involved, however, if the Commission participates it shall not assess its costs or expenses to the Contractor under this subsection without the Contractor's written consent.
- 23.2 If, in the Contractor's opinion, the equipment, materials or information

# **GENERAL PROVISIONS FOR CONTRACTS**

mentioned in Section 22 above is likely to or becomes the subject of a claim of infringement of a United States patent or copyright, then without diminishing the Contractor's obligation to satisfy any final award, the Contractor may, with the Chairman's written consent, substitute other equally suitable equipment, materials and information, or at the Contractor's option and expense, obtain the right for the Contractor or the Commission to continue the use of such equipment, material and information.

### 24. ARIZONA LAW

This Contract is governed by the laws of the State of Arizona including the Arizona Procurement Code (A.R.S. Title 41, Chapter 23) and the Arizona Procurement Code Rules and Regulations (A.C.C.R. Title 2, Chapter 7).

#### **GENERAL PROVISIONS FOR CONTRACTS**

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